# Introduction to Aseptic Technique and Sterility in the IV Room

- USP <797> Sterile compounding Course 2025
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# What is Sterile Compounding ?

WHAT → free from **living microorganisms.**

HOW → preparing medications in a **sterile, controlled environment**

WHY → to **prevent** microbial contamination.

LIKE → **injections, IV infusions & eye drops.**

Personal responsibilities:

- **correct ingredient identity**
- **purity**
- **right strength**
- **sterility and for dispensing them in**
- **appropriate containers**
- **labeled accurately**
- **appropriately for the end user**

Standard procedures in IV compounding include:

- **Preparation in a clean room**.
- **Use of aseptic techniques**
- **Regular training and competency assessments**

# What is Contamination

- Most common contaminant is **personnel**, even those who use good aseptic techniques, shed enormous numbers of particles from **themselves** and their **clothing** and these particles are laden with **microorganisms.**
  - A person harbors an average of **150-200 classes of bacteria.**
  - A person sheds **5 million squamous cells per day.**
  - Walking through the area will create a plume of **turbulent air 30 feet behind.**
  - A person's hands have **100,000 bacteria/mm2**.
- USA 2001 - 2013:
  - identified 19 outbreaks linked to pharmacy sterile compounds.
  - At least 1000 cases, including deaths.
- UK 2012:
    - 2012 fungal meningitis outbreak linked to the New England Compounding Center (NECC), which resulted in over 100 patient deaths.

# ISO classification in sterile compounding

- The ISO standards for air quality in controlled environments (**The lower the ISO # the cleaner**).
- Facilities used for compounding sterile preparations must be designed so that air quality improves with movement through separate operational areas to the **Primary Engineering Controls (PEC).**
- Classified areas in which the air quality is controlled include **ante-rooms**, **buffer rooms**, and **Primary Engineering Controls (PECs)**.

**Table 1. ISO Classification of Particulate Matter in Room Air**

(particles 0.5 µm and larger per cubic meter)

| ISO Class | Particle Count |
|---|---|
| 3 | 35.2 |
| 4 | 352 |
| 5 | 3,520 |
| 6 | 35,200 |
| 7 | 352,000 |
| 8 | 3,520,000 |

# Facility Layout Requirements & ISO classifications

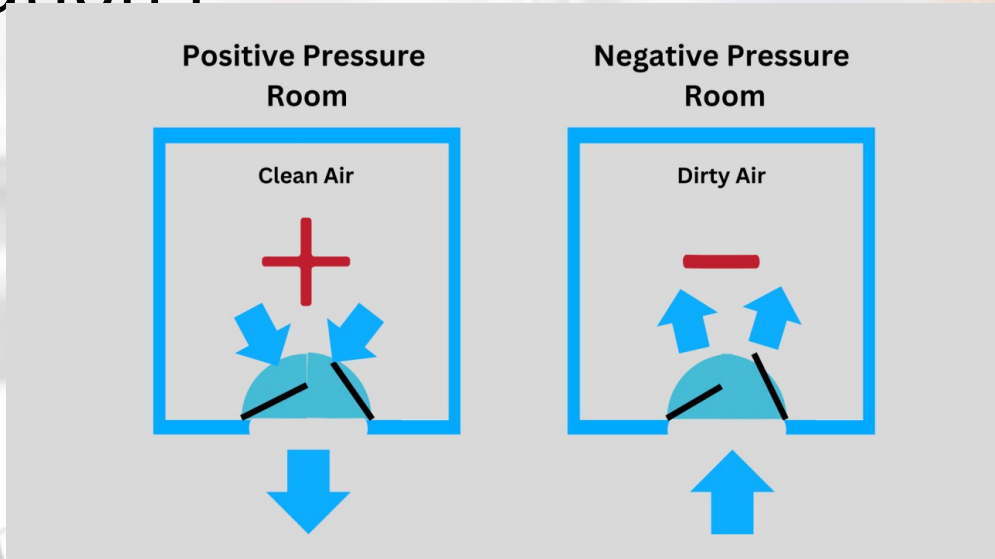
- **Secondary engineering controls (SEC):**

  **1- Ante-room:** (*ISO8, positive pressure air control*)
  - A small transitional space (airlock) between a contaminated/construction area and clean spaces, designed to control airflow and prevent the spread of airborne pathogens, dust, and debris, allowing staff to safely don/doff protective gear (PPE).

  **2- Buffer room:** (*ISO7, positive or negative pressure air control*)
  - a critical, controlled space located between less clean areas and the most sterile environments (engineering control or hood), acting as a transitional zone to prepare materials and personnel for sterile compounding, minimizing contamination.

- **Primary Engineering Controls PEC (Hood):** (*ISO5, positive or negative pressure air control*)
  - physical barriers and equipment that isolate hazards, protect workers, products, and the environment from contamination, ensuring sterile compounding (USP <797>) and safe handling of hazardous drugs (USP <800>) by controlling airborne particles and drug vapors at the source, making them the most effective safety measure.

# Facility Layout Requirements & ISO classifications




- **<u>positive pressure room:</u>**
  - is essential for preparing **non-hazardous sterile medications** to protect the product from external contamination. The higher pressure inside the room **creates an outward airflow**, preventing unfiltered, potentially contaminated air from entering the sterile area.

- **<u>negative pressure room:</u>**
  - creates lower air pressure than adjacent areas, **causing air to flow into it**, which contains **hazardous drugs (HDs) or potent compounds**, preventing their escape into cleaner zones

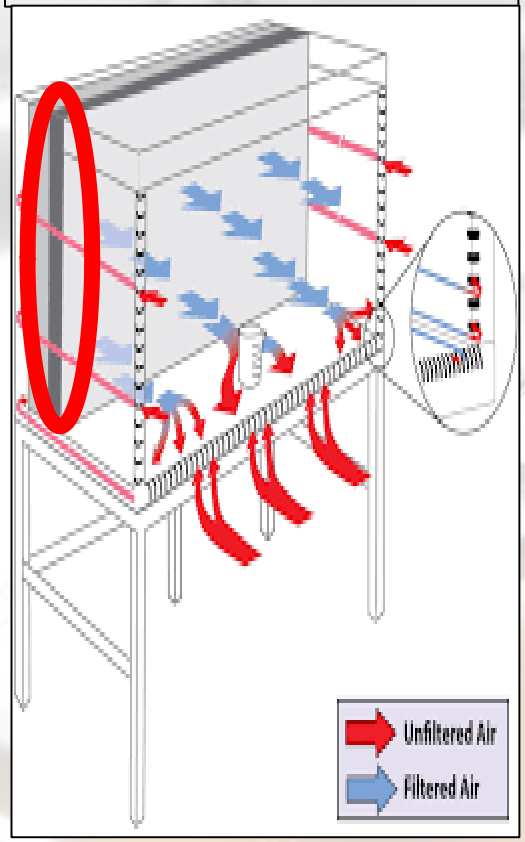
# Primary engineering controls (PEC)

- specialized devices, like laminar flow hoods or isolators, that create ultra-clean, **ISO Class 5** environments using **HEPA-filtered air** for ste compounding, protecting the product from contamination by providing unidirectional airflow and filtering airborne particles.

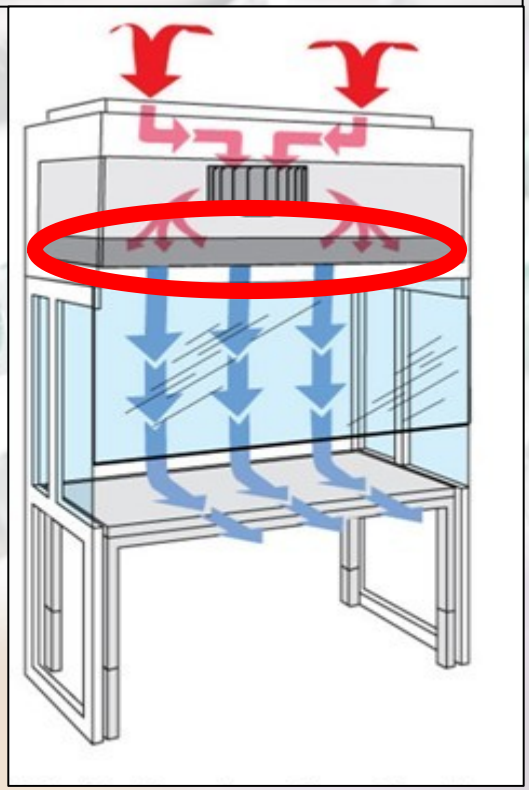
- Air pressure Types:
  - Positive → non-hazardous compounding.
  - Negative → hazardous compounding.

# Types of Primary engineering controls (PEC)

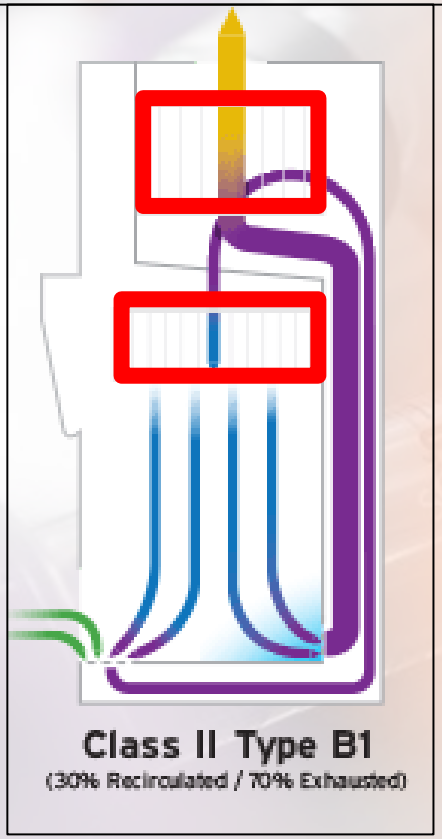
**Horizontal Laminar Air Flow (positive cabinet)**




**Vertical Laminar Air Flow (positive cabinet)**



**Biosafety cabinets (negative cabinet)**

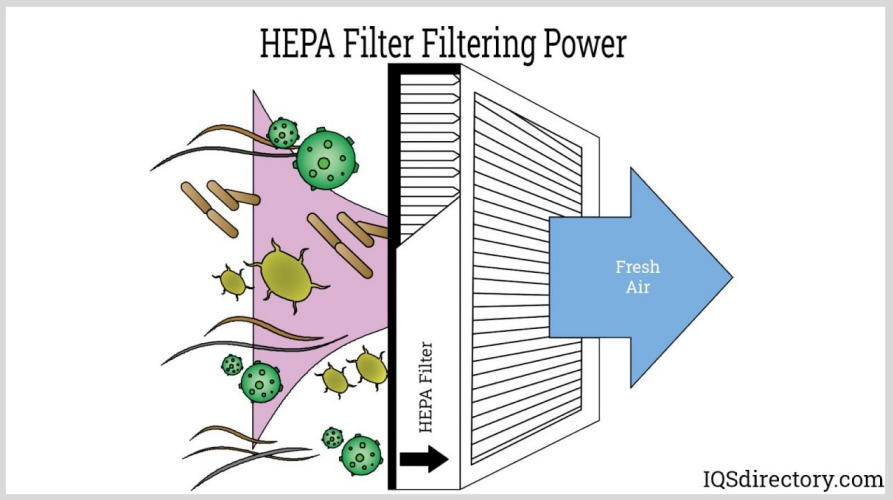


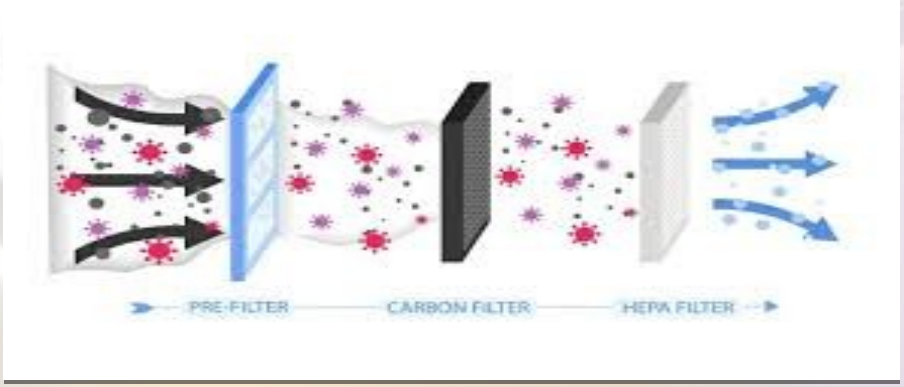

HEPA Filters

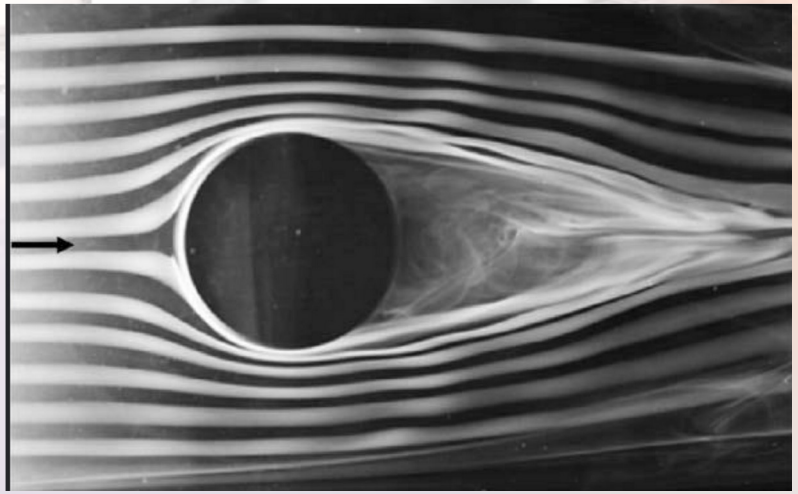
# High-Efficiency Particulate Air (HEPA) Filters

- HEPA  filters are essential in sterile compounding for creating ISO Class 5 environments by removing at least **99.97%** of airborne particles

- including dust, bacteria, and mold, ensuring the purity of compounded sterile preparations (CSPs).



# Personal Protective Equipments (PPE)

- PPE are essential to protect staff and patients from contamination, especially when handling hazardous drugs (HDs) or making sterile preparations, with proper **donning/doffing**, **fit-testing**, and **usage protocols** crucial for preventing infection and exposure.
  - **gloves** (double-gloving for hazardous drugs)
  - **gowns** (Chemo-rated gown over sterile gowning for hazardous drugs)
  - **masks** (N95/surgical)
  - **hair/shoe covers**
  - **eye protection** (goggles/face shield)

Goggles and face shield
Coverage for hair and beards
Fit-tested N95 respirator mask
Gown that closes in the back or is fully covered in back
2 Pairs of chemotherapy-tested[5] gloves
Chemo-rated[6] impervious gown that extends below knees.
Shoe or boot covers

# COVID-19 PPE

## How do I safely wear my PPE?

More than one method of donning and doffing may be acceptable. Refer to your healthcare facility's guidance.

Consider having someone observe your donning and doffing to ensure appropriate steps are followed.

If hands become contaminated during doffing (such as by contacting the outside of the PPE), immediately perform hand hygiene before resuming doffing.

Disposable PPE can be discarded in regular trash unless heavily soiled with blood or other bodily fluids.

**Wash hands.**
Perform hand hygiene with soap and water or alcohol-based hand sanitizer.

**Put on mask.**

- Straps should be secured at the crown of the head and base of the neck, or behind the ears.
- Fit the nosepiece by pressing with both hands to form around the nose.
- Ensure mask fits tighly to the face and extends below the chin.

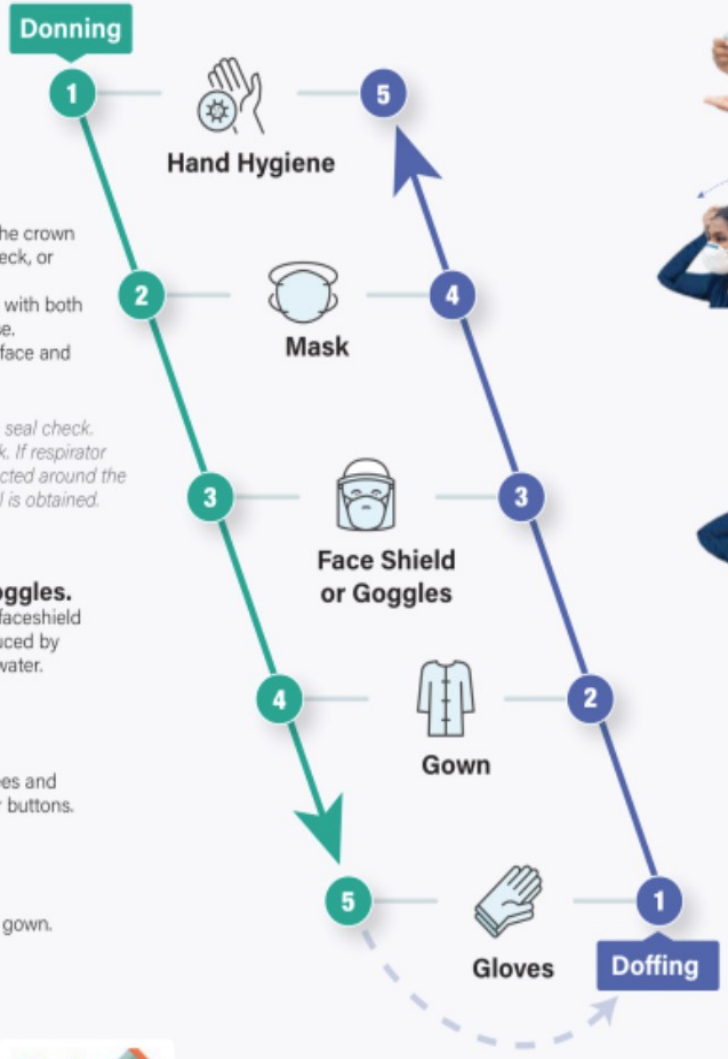
*Seal Check*

*If wearing a respirator, perform a seal check. Cup your hands around the mask. If respirator fails to collapse or airflow is detected around the mask, readjust until a proper seal is obtained.*

**Put on face shield or goggles.**
If you wear glasses under your faceshield or goggles, fogging can be reduced by washing lenses with soap and water.

**Put on isolation gown.**
Gown should cover neck to knees and arms to wrists. Secure all ties or buttons.

**Put on gloves.**
Extend to cover the wrist of the gown.



**Wash hands.**
Perform hand hygiene with soap and water or alcohol-based hand sanitizer.

**Remove mask.**

- Remove lower strap followed by upper strap. Pull away from face without touching the front of the mask.
- Or remove by unhooking the ear loops.
- Discard or place in storage or reprocessing container.

**Remove face shield or goggles.**

- Lift the strap from the back and pull up and away from the head.
- Avoid touching the front of the goggles or face shield.
- Discard or place in reprocessing bin, if reusable.

**Remove gown.**

- Unfasten gown and pull down and away from the body, rolling gown inside out. (Avoid touching the outside of gown.)
- Discard or place in reprocessing bin, if reusable.
- If wearing disposable gown, gloves and gown can be removed together

**Remove gloves.**

- Remove first glove by pinching the palm of the glove and peeling off.
- Hold the removed glove in gloved hand. Insert finger under the remaining glove at the wrist.
- Peel off second glove over first glove. Discard.

A video demonstration of donning and doffing can be found here: https://www.lifebox.org/ppe/

lifebox

# How Maximise PPE ?

How to Handwash?
WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB
Duration of the entire procedure: 40-60 seconds
0
Wet hands with water;
1
Apply enough soap to cover all hand surfaces;
2
Rub hands palm to palm;
3
Right palm over left dorsum with interlaced fingers and vice versa;
4
Palm to palm with fingers interlaced;
5
Backs of fingers to opposing palms with fingers interlocked;
6
Rotational rubbing of left thumb clasped in right palm and vice versa;
7
Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;
8
Rinse hands with water;
9
Dry hands thoroughly with a single use towel;
10
Use towel to turn off faucet;
11
Your hands are now safe.

- Goal: reducing the microbial burden.
- DO:
  - Hands must be cleansed carefully
  - personal protective equipment worn correctly in order
    - Doning (Dirtiest → cleanest)
    - Doffing (Cleanest → Dirtiest)

- DON'T:
  - Infected skin (e.g., rashes, cuts, sunburn, and weeping sores)
  - people with active respiratory infections shed
  - wear cosmetics or makeup, Jewelries causes more particles are shed.

# Aseptic technique
# “Preparing”

- Clean all working flat surfaces and the PEC with **70% isopropyl alcohol**
- Use proper aseptic techniques to clean PEC
- **Assemble** all necessary supplies in the hood checking each for packaging damage, expiration dates, and particulate material (enter once and exit once).
- Use only **pre-sterilized** needles, syringes, and tubing for medication transfers.
- Remove the dust covering from supplies before placing them in the hood.

# Cleaning Hood

https://www.youtube.com/watch?v=31XhjVU2-u8

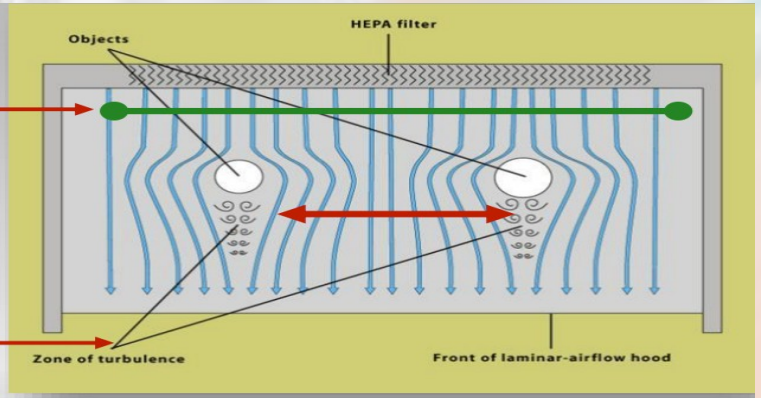
# Item Placement Inside PEC

**First Air Zone**

Nothing to be placed between the HEPA filter and the critical compounding zone

**Zone of Confusion**

Turbulent area downstream of an obstruction possible source of cross contamination

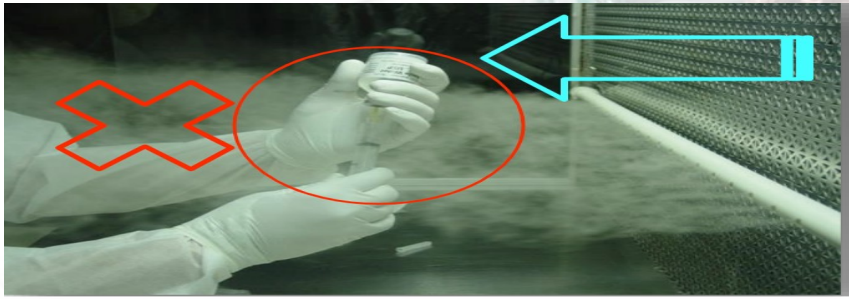


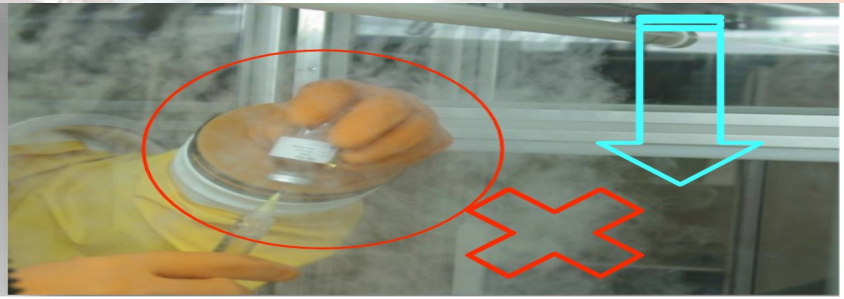

- **No objects** between the HEPA filter and the sterile surfaces, and that there is adequate space between objects.
- Place the smaller supplies closer to the HEPA filter and larger supplies farther away from the filter.
- Swab all surfaces that require entry (puncture) with 70% isopropyl alcohol or betadine solution. **Avoid excess alcohol** or lint that might be carried into the solution.
- Do all manipulations at least **6 inches** inside the outer edge of the hood.

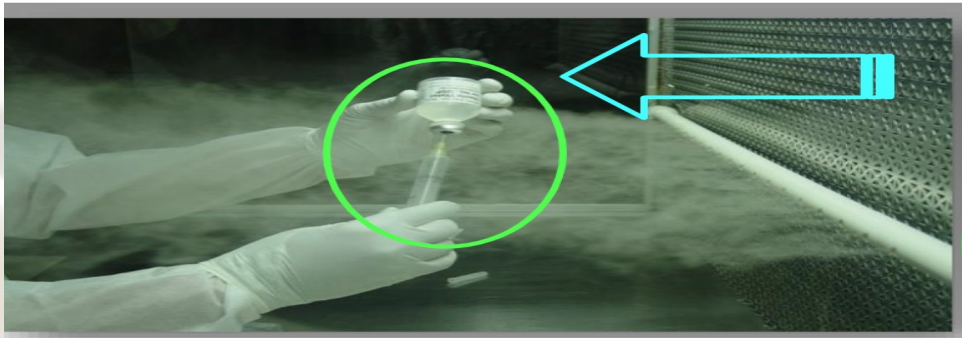
# Aseptic technique

- Give close attention to **hand position** and the direction of air flow over injection ports or objects being manipulated.

- Minimize hand movements within the hood to prevent **air turbalance.**

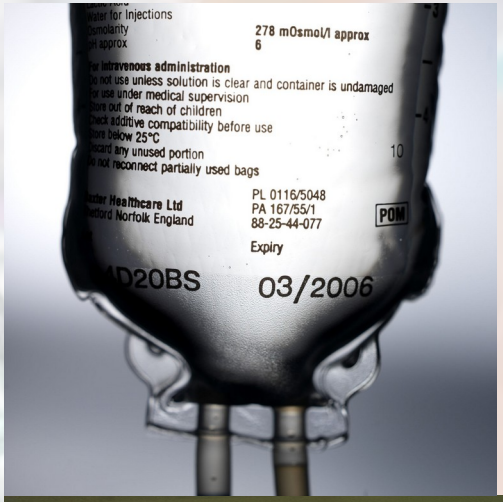






# Aseptic technique

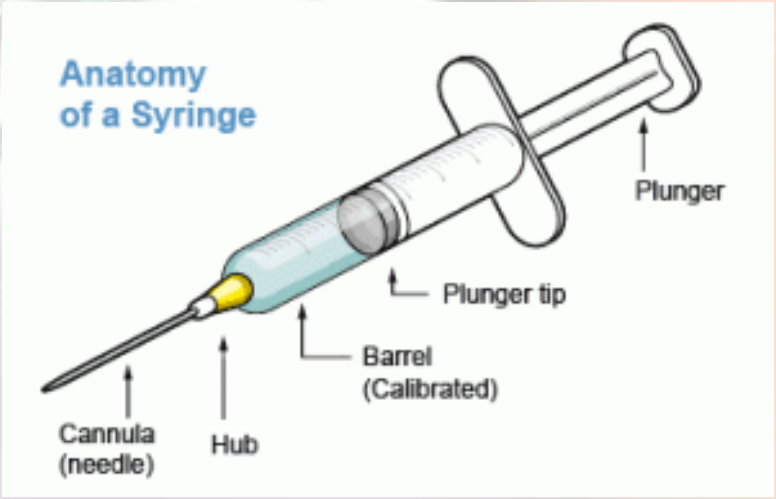
- Do not remove the hands from the hood until the compounding procedure is complete and the final inspection of the formulation has been made.
- Examine all formulations before removing them from the hood.
- Place all syringes and needles in puncture-proof containers and dispose of them according to institutional procedures.



# Syringes and Needles

- Syringes are available in sizes ranging from 1 to 60 mL

- In most cases, you should use the smallest syringe possible to draw up your complete volume;



# Syringes and Needles

- Needle size is determined by **gauge** (higher number = lower diameter of needle tip) and **length** (in inches).
- **Never touch** any part of the needle (except the packaging and covers).
- **Peel and open** needle packages within hood to maintain sterility (Tearing the paper introduces paper particles into the hood, leading to contamination).
- Needles and syringes must be disposed of in the **sharps container.**

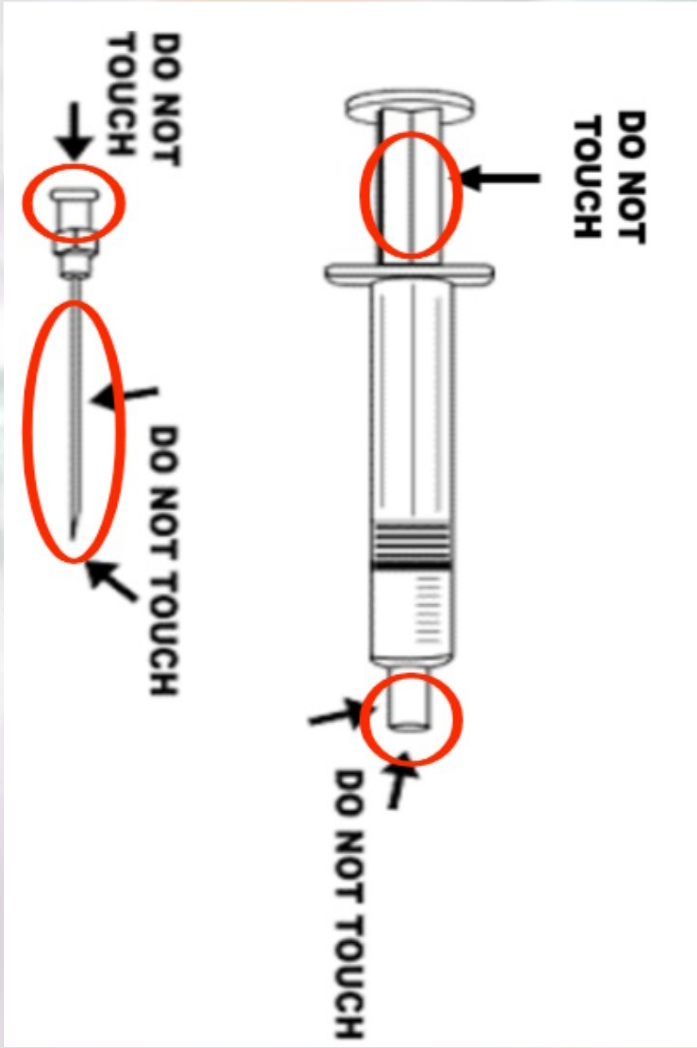
# Aseptic technique

- To assemble needles and syringes, **peel** back the protective coverings and attach the needle and syringe, twisting to lock in place.

- All manipulations must be done **without touching critical sites**, parts that will contact the sterile solution (syringe tip, the plunger piston, and the needle shaft/hub).

- Manipulations must occur inside (at least **6 inches)** a certified laminar airflow workbench (LAFW) or other Primary Engineering Control (PEC).

- **Single-Use and Discard**



# Vials

- Rub rubber stopper with a sterile 70% isopropyl alcohol Draw Air:
- using a syring, draw air equal to the desired dose of medication.
- Insert the needle into the rubber stopper, ensuring the tip is above the fluid level, and push the air into the vial.
- Invert the vial and syringe and pull back the plunger to the correct measurement line.
- Tap the syringe gently to move any air bubbles to the top, then gently push the plunger to expel the air back into the vial.
- Remove the needle from the vial, place the cap back on the needle if you plan to set it down temporarily, and dispose of the syringe and needle in a sharps container after use.

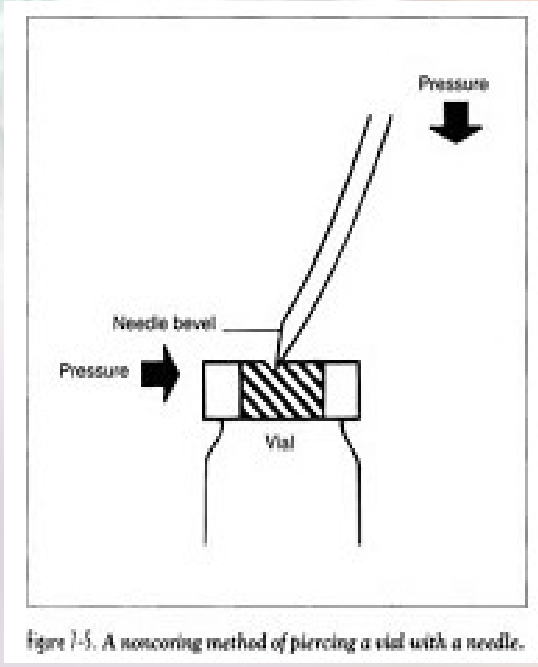
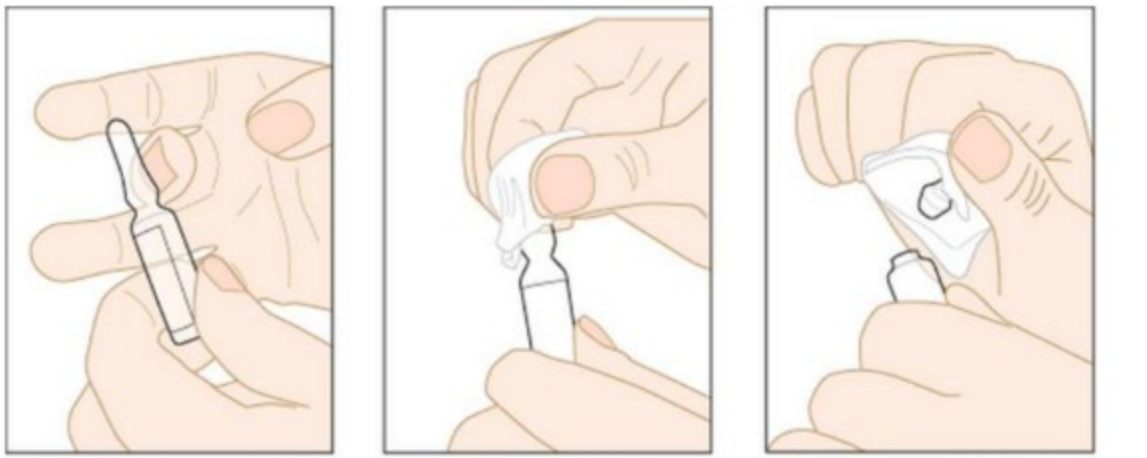


Figure 7-5. A noncoring method of piercing a vial with a needle.

https://www.youtube.com/watch?v=McNHLZlNoiA

# Ampoules

- Tap Down Liquid
- Clean the Neck with a sterile 70% isopropyl alcohol pad.
- Use a piece of sterile gauze, an alcohol pad to protect your fingers from laceration.
- Snap Away
- Use a Filter Needle (typically 5-micron) to your syringe.
- Aspirate Carefully: Slowly and steadily pull back on the plunger to withdraw the required amount of medication.
- Remove and Replace: Remove the filter needle from the ampoule. Discard the filter needle in a sharps container and replace it with an appropriate administration needle or luer-lock cap before injecting the patient.
- Check for Particles: Visually inspect the syringe against a lighted background
- Proper Disposal in sharps container.



https://www.youtube.com/shorts/oLhCK3psOos

# Cleaning, Disinfection & Sterility Assurance

| Site | Minimum Frequency |
|---|---|
| ISO Class 5 PEC | Beginning of each shift<br>Before each batch<br>Every 30 minutes when compounding<br>After spills<br>When surface contamination is known or suspected |
| Counters and easily cleanable work surfaces | Daily |
| Floors | Daily |
| Walls | Monthly |
| Ceilings | Monthly |
| Storage shelving | Monthly |

# Risk Level Classification

The potential risk is based on the **danger of exposing** multiple patients to microbial bioburden and based on microbial growth factors influenced by product storage time, temperature and product ability to support microbial growth, surface and time exposure of critical sites, and microbial bioburden in the environment.

## Low-Risk CSPs

1-CSPs are compounded using aseptic technique within an **ISO Class 5 PEC.**

2-Each container, including the final container, may not be entered **more than twice to prepare the CSP.**

3-Compounding is limited to **aseptic manipulations** of disinfected containers using sterile needles and syringes.

## Medium-Risk CSPs

1-**Multiple doses** of sterile products combined or pooled to prepare a product that will be administered either to multiple patients or one patient on multiple occasions.

2-**More than three** commercially available sterile products are used to produce the compound.

3-**More complex** compounding processes.

## High-Risk CSPs

1-Prepared from **nonsterile ingredients**.

2-Compounded using a **nonsterile device** prior to terminal sterilization.

3-Containing **nonsterile water** that are stored for more than 6 hours before sterilization.

4-Exposed to conditions **worse than ISO Class 5** air quality for longer than 1 hour.

5-Containing **bulk ingredients** whose chemical purity and content strength are **not verified** by labeling and documentation from suppliers or by direct determination.

6-Prepared by compounding personnel who are **improperly garbed or gloved.**

# Personnel Compounding Competency

## Observational Competency

. Proper **hand hygiene** technique.

. Proper **gloving and garbing** technique.

. Proper **aseptic technique**.

. Proper **cleaning and disinfecting** procedures.

. Competency in the **compounding** of hazardous drugs.

## Glove Fingertip Testing

. Preform **Immediately** upon completion of these procedures End of doning).

. This test must be successfully completed **three times initially.**

. then at least every **12 months for low-med risk CSPs.**

. **6 months for high risk CSPs**

## Media-Fill Testing

. **Low-Risk CSPs every 12 months.**

. **Medium-Risk CSPs every 12 months.**

. **High-Risk CSPs every 6 months.**

. prefered to be performed at the **end of a shift.**

thank you